

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet, the method comprising the steps of:
detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a colorant; and
determining the formulation orientation of the tablet on the basis of the color detected.
2. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet, the method comprising the steps of:
detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a dark colorant; and
determining the formulation orientation of the tablet on the basis of the color detected.
3. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet, the method comprising the steps of:
detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a dark colorant and another formulation layer contains a light colorant; and
determining the formulation orientation of the tablet on the basis of the color detected.
4. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a formulation layer that contains a drug ingredient and having an opposite end portion containing a formulation layer without a drug ingredient, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

5. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a formulation layer that contains a drug ingredient and having an opposite end portion containing a formulation layer without a drug ingredient, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one formulation layer without a drug ingredient contains a dark colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

6. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a formulation layer that contains a drug ingredient and having an opposite end portion containing a formulation layer without a drug ingredient, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the

formulation orientation of the tablet, wherein a formulation layer without a drug ingredient contains a dark colorant and another formulation layer that contains a drug ingredient contains a light colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

7. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a dispensable formulation-forming layer and having an opposite end portion containing an expanding polymer formulation layer, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one of the one or another formulation layers contains a colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

8. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a dispensable formulation-forming layer and having an opposite end portion containing an expanding polymer formulation layer, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one expanding polymer formulation layer contains a dark colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

9. **(Withdrawn)** A method of detecting the formulation orientation of a multi-layer capsule-shaped tablet having an end portion containing a dispensable formulation-forming layer and having an opposite end portion containing an expanding polymer formulation layer, the method comprising the steps of:

detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein an expanding formulation layer contains a dark colorant and a dispensable formulation-forming layer contains a light colorant; and

determining the formulation orientation of the tablet on the basis of the color detected.

10. **(Withdrawn)** A method of detecting The formulation orientation of a three-layer capsule-shaped tablet having an end portion containing a first formulation layer that contains a drug ingredient, a middle portion containing a second formulation layer that contains a drug ingredient, and an opposite end portion containing a third formulation layer without a drug ingredient, the method comprising the steps of

including at least one colorant in one formulation layer of the tablet;

detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet; and

determining the formulation orientation of the tablet on the basis of the color detected.

11. **(Withdrawn)** A method of detecting the formulation orientation of a three-layer capsule-shaped tablet having an end portion containing a first formulation layer that contains a drug ingredient, a middle portion containing a second formulation layer that contains a drug ingredient, and an opposite end portion containing a third formulation layer without a drug ingredient, the method comprising the steps of:

including a first colorant in one of the first or second formulation layers of the tablet;

including a second colorant in the third formulation layer;

detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet; and

determining the formulation orientation of the tablet on the basis of the color detected.

12. **(Withdrawn)** The method of claim 11 wherein said first colorant is light and said second colorant is dark.

13. **(Withdrawn)** A method of detecting the formulation orientation of a three-layer capsule-shaped tablet having an end portion containing a first dispensable formulation layer, a middle portion containing a second dispensable formulation layer, and an opposite end portion containing an expandable polymer formulation layer, wherein at least one of the first and second layers contains a drug ingredient, the method comprising the steps of:

including a first colorant in one of the first or second dispensable formulation layers of the tablet;

including a second colorant in the third expandable polymer formulation layer;

detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet; and

determining the formulation orientation of the tablet on the basis of the color detected.

14. **(Withdrawn)** The method of claim 13 wherein said first colorant is light and said second colorant is dark.

15. **(Withdrawn)** A method of preparing a multi-layer capsule-shaped tablet having a push end and a dispensing end for laser drilling of a delivery port in said dispensing end, the method comprising the steps of:

detecting the formulation orientation of the tablet by detecting the color at a spot location on a side of the tablet corresponding to one or another formulation layer depending on the formulation orientation of the tablet, wherein at least one layer contains a colorant;

determining the formulation orientation of the tablet on the basis of the color detected;

passing the tablets through a tablet rectifier wherein the orientation of any improperly oriented tablets is rectified and the orientation of any properly oriented tablets is maintained; and

collecting the uniformly oriented tablets from said tablet rectifier for transportation to a laser drilling station.

16. **(Withdrawn)** The method of claim 15 wherein the colorant is a dark colorant.

17. **(Withdrawn)** The method of claim 16 wherein the formulation layer containing the dark colorant does not contain a drug ingredient and another formulation layer containing a drug ingredient also contains a light colorant.

18. **(Currently Amended)** A method of making a three-layer capsule-shaped tablet comprising:

formulating a first layer containing a drug ingredient and a second layer containing a drug ingredient, wherein one of the layers comprises a first colorant;

formulating a non-drug ingredient containing third layer comprising a second colorant that is distinguishable from the first colorant or from no color and not containing any drug ingredient;

compressing the first, second and third layers into a capsule-shaped osmotic wherein the first layer is located at one end of the capsule-shaped osmotic tablet and the third layer is located at the other end of the capsule-shaped osmotic tablet and the second layer is located between the first layer and the third layer such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored layer depending on the formulation orientation of the tablet; and

detecting the formulation orientation of the tablet with a color detector directed at a spot location on the side of the tablet.

19. **(Previously Presented)** The method of claim 18 wherein the first colorant is light and the second colorant is dark.

20. **(Currently Amended)** A method of making a three-layer capsule-shaped tablet comprising:

formulating a first layer containing a drug ingredient and not containing any colorant;
formulating a second layer containing a drug ingredient and a first colorant, the first colorant being complementary to no color;

formulating a third layer containing a second colorant that is distinguishable from the first colorant or from no color and not containing any drug ingredient;

compressing the first, second and third layers into a capsule-shaped osmotic tablet the first layer is located at one end of the capsule-shaped osmotic tablet and the third layer is located at the other end of the capsule-shaped osmotic tablet and the second layer is located between the first layer and the third layer such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored layer depending on the formulation orientation of the tablet; and

detecting the formulation orientation of the tablet with a color detector directed at a spot location in the side of the tablet.

21. **(Cancelled)** A method of making a multi-layer tablet comprising:

adding a first colorant to one formulation layer containing a drug ingredient proximately positioned at a dispensing end of the multi-layered tablet, the first colorant being complementary to no color;

adding a second colorant to at least one formulation layer not containing any drug ingredient proximately positioned at a push end of the multi-layered tablet, the second colorant distinguishable from the first colorant or from no color;

compressing the formulation layers into a capsule-shaped osmotic tablet such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet, and

detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet.

22. **(Currently Amended)** A three-layer capsule-shaped tablet comprising:

first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, one of the first or second layers also containing a first colorant;

a third layer formulation containing a second colorant that is distinguishable from the first colorant or from no color and not containing any drug ingredient wherein the first, second and third layers are compressed into a capsule-shaped osmotic tablet having the first layer formulation located at one end of the capsule-shaped osmotic tablet and the third layer formulation located at the other end of the capsule-shaped osmotic tablet and the second layer located between the first layer formulation and the third layer formulation such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet and wherein the formulation orientation of the tablet is detected by a color detector directed at the spot location on the side of the tablet.

23. **(Previously Presented)** The tablet of claim 22 wherein the first colorant is light and the second colorant is dark.

24. **(Original)** The tablet of claim 23 further comprising a membrane surrounding the compressed layers through which the first and second colorant are detectable.
25. **(Previously Presented)** The tablet of claim 24 further comprising a delivery port drilled into the membrane at a location proximate to the first layer.
26. **(Original)** The tablet of claim 25 further comprising a drug overcoat applied onto the surface of the membrane.
27. **(Currently Amended)** A three-layer capsule-shaped tablet comprising:
a first layer formulation containing a drug ingredient and not containing any colorant;
a second layer formulation containing a drug ingredient and a first colorant, the first colorant being complementary to no color;
a third layer formulation containing a second colorant that is distinguishable from the first colorant or from no color and not containing any drug ingredient wherein the first, second and third layers are compressed into a capsule-shaped osmotic tablet wherein the first layer formulation is located at one end of the capsule-shaped osmotic tablet and the third layer formulation is located at the other end of the capsule-shaped osmotic tablet and the second layer is located between the first layer formulation and the third layer formulation such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet; and
wherein the formulation orientation of the tablet is detected by a color detector directed at the spot location on the side of the tablet.
28. **(Previously Presented)** The tablet of claim 27 wherein the first colorant is light and the second colorant is dark.
29. **(Original)** The tablet of claim 28 further comprising a membrane surrounding the compressed layers through which the first and second colorant are detectable.

30. **(Previously Presented)** The tablet of claim 29 further comprising a delivery port drilled into the membrane at a location proximate to the first layer.
31. **(Original)** The tablet of claim 30 further comprising a drug overcoat applied onto the surface of the membrane.
32. **(New)** The method of claim 18 wherein said second layer comprises a larger concentration of drug ingredient than said first layer.
33. **(New)** The method of claim 18 wherein said first and second layers comprise methylphenidate chloride.
34. **(New)** The method of claim 18 wherein said first layer comprises about 9% to about 10% by weight methylphenidate chloride and said second layer comprises about 13% to about 14% by weight methylphenidate chloride.
35. **(New)** The method of claim 20 wherein said second layer comprises a larger concentration of drug ingredient than said first layer.
36. **(New)** The method of claim 20 wherein said first and second layers comprise methylphenidate chloride.
37. **(New)** The method of claim 20 wherein said first layer comprises about 9% to about 10% by weight methylphenidate chloride and said second layer comprises about 13% to about 14% by weight methylphenidate chloride.
38. **(New)** The three-layer tablet of claim 22 wherein said second layer comprises a larger concentration of drug ingredient than said first layer.
39. **(New)** The three-layer tablet of claim 22 wherein said first and second layers comprise methylphenidate chloride.

DOCKET NO.: ALZA-0022
Application No.: 09/324,343
Office Action Dated: March 11, 2005

**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

40. (New) The three-layer tablet of claim 22 wherein said first layer comprises about 9% to about 10% by weight methylphenidate chloride and said second layer comprises about 13% to about 14% by weight methylphenidate chloride.

41. (New) The three-layer tablet of claim 27 wherein said second layer comprises a larger concentration of drug ingredient than said first layer.

42. (New) The three-layer tablet of claim 27 wherein said first and second layers comprise methylphenidate chloride.

43. (New) The three-layer tablet of claim 27 wherein said first layer comprises about 9% to about 10% by weight methylphenidate chloride and said second layer comprises about 13% to about 14% by weight methylphenidate chloride.